

Global Pharma US & EU Outlook 2015: First –In- Class Innovations and Cost Optimization Plays Major Role In Shaping Up Business for Large Cap Pharmaceutical Companies

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Abstracts

Strategy Diversification Divested: Productivity measurements, Divestment of non-core assets resulting in healthy Cash position- Will accelerate Next wave of targeted acquisition

In the recent years several new therapies have been approved in the area of diabetes (SGLT-2, GLP-1 agonists), Multiple Sclerosis, HCV, melanoma and breast cancer from major pharmaceutical companies. Many of them are expected to reach multibillion dollars peak sales in the near-term which is likely to compensate the patent expiry loss in top-line revenue. Novel mechanisms like anti-PD1, anti-PCSK9 and CDK inhibitors have also got exclusive attention by large cap Pharma companies. Most companies are in race to acquire assets in these hot therapy areas. Companies who already have these assets are investing heavily in clinical development programs. The interest in pursuing opportunities in Oncology therapy is unhindered for all major Pharma companies. Research investments in oncology likely to continue for several more years due to the significant unmet need exist in this area.

But for a few companies, patent expiry impact continues to haunt the top-line and they are finding it difficult to replace declining sales with Proprietary pipeline products. Beyond 2013, the impact of patent loss will further aggravate the revenue decline. They have chosen strategies of prioritization pipeline assets, cost efficiency measures, divestment of non-core assets which yield poor margins and increase focus on therapy areas where they have already proven its mettle. Increase in dividend payout and share repurchase are some near term measures where they are actively participating. Gain in

financial strength through divestment of non-core assets (OTC, Animal Health, Consumer health, Diagnostics) will be utilized in pursuing opportunities in high margin therapy areas. At the same time it has becoming more difficult to find such lucrative assets because they are scarce and if available are trading at very high premium in speculation of getting acquired (ex. Roche-Alexion). Going forward, Economies of Scale will also play a major role in swapping the non-core business among major pharma including Vaccines, OTC and animal health to improve margins.

Global Pharma continues to remain attractive due to management efforts on the restructuring of entire business model, cost efficiency measures, de-consolidation, acquisition of high value targeted assets, share repurchase program and dividend policy.

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1. ASTRAZENECA: LATE STAGE PIPELINE MATURING; FOCUSED DEVELOPMENT ON RESPIRATORY, PSORIASIS AND ANTI-PD1 WILL SUPPORT LONG TERM GROWTH

Late stage development is positive but near term pressure immense

R&D Strategy

Long-term CV study and R&D Updates

Brilinta preferred over Plavix in NSTEMI-ACS patients in the US

Strengthening Business in Diabetes: Acquisition from BMJ

Late Stage Development Program

Selumetinib (Phase III, NSCLC, MEK inhibitor, Array Pharma)

Lesinurad (Phase III, URAT1 inhibitor/Hyperuricemia in Gout): did not reduce gout flares but biomarker uric acid level met the end point for approval

Immunotherapy anti CTLA and anti-PD1 will strengthen the franchise long-term

Olaparib (PARP Inh, Ovarian cancer)- FDA approval

AZD9291 (once daily, oral Tyrosine kinase inhibitor, second-line NSCLC)

Inflammation pipeline: Benralizumab (IL-5R antibody, severe asthma and COPD)

Competitive landscape of cytokine targeted therapies (Tralokinumab, Dupilumab, Lebrikizumab, Mepolizumab)

Brodalumab (IL-17RA antibody, Psoriasis, Psoriatic arthritis, Phase III)

Outlook of respiratory franchise going forward: Symbicort, Pearl and Almirall

Anti-infective franchise update (AZD0914)

Nexium OTC approved and generic entry in 2015

The impact of competition on Faslodex

Key milestones

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2. GLAXOSMITHKLINE: RELIANCE ON LOW MARGIN CONSUMER HEALTH AND VACCINES; UNABLE TO REVIVE RESPIRATORY FRANCHISE

Respiratory business competitive and large outcome trials became futile

Cost savings to keep up the operating margins and Potential ViiV IPO to fund NVS JV buy-out

Our views on the recently approved drugs from GSK

Eperzan/Tanezum (Albiglutide): Superior efficacy, better tolerability, ease of administration and compliance benefit should position Albiglutide better than competition in earlier lines of treatment

Mepolizumab (IL-5 inhibitor, UR, once monthly, severe eosinophilic asthma)

Competitive Landscape in severe asthma

Advair Generics

Key milestones

Table 1: Bydureon, albiglutide & Victoza Clinical data comparison

3. MERCK: ANTI-PD1 AND HCV WILL REMAIN GROWTH DRIVERS GOING FORWARD!!

IMPROVE-IT Outcome data positive, boosted confidence on other aggressive LDL reducing antibodies therapy

TECOS should help DPP-IV expand their share in a fast growing but highly genericized diabetes market

Acquisition of Cubist for \$9.1b will fortify MRK's anti-infective acute hospital care franchise

Collaboration with Bayer for novel cardiovascular assets (\$1b+)

Ebola Vaccine acquisition and development

Keytruda Potential

HCV Therapy (grazoprevir/elbasvir, PhIII): targeted for patients who do not tolerate market leading Sovaldi

Regulatory Developments – Gardasil, Belsomra, Grass and Ragweed sublingual allergy tablets, Sugammadex, Odanacatib

Isentress and anti-retroviral development

Diabetes Franchise – Ertugliflozin, Januvia/Janumet, Omarigliptin

Keytruda in Second-line NSCLC: Potential additional indications –breast cancer

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Key milestones

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Acquisition of Sigma-Aldrich for \$17b would add over \$2.1b in topline

Strategic alliances with PFE to develop Immuno-oncology pipeline- anti-PD1

Erbitux in first line CRC

Erbitux Biosimilar threat is limited due to different manufacturing process in EU/US

Gonal-F- Biosimilar competition

Performance materials

Merck Millipore in life sciences tool market (€2.6b)

Consumer Health (€472m - ~4% of total sales)

Emerging market continues to support the company growth going forward (€1.8b)

Key Milestones

Table 1: Merck Serono PhII and PhIII pipeline assets

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LCZ696 (valsartan with neprilysin inhibitor; twice daily) in chronic heart failure patients:

Superiority can command higher prices and reimbursement

Rationale for fixed dose combination and Paradigm HF

Patent expiry pressure immense

Targeted and cellular therapy approach in Oncology

CART Technology

Gilenya in Multiple Sclerosis continues to be key growth driver but market ramp up of

Tecfidera (BiogenIdec) is extraordinary despite PML issue

Lemtrada was effective but disease progressed after discontinuation

SERELAXIN (RLX-030) in Acute Heart Failure – Unmet need but FDA rejected the approval for more efficacy data

Signifor LAR – Approved in Cushing's disease and in acromegaly: Sandostatin LAR

Replacement ready in active acromegaly

Signifor/ Pasireotide will penetrate in patients inadequately controlled on Sandostatin.

Signifor LAR will take up market share from Sandostatin LAR before the patent expiry in 2017

Secukinumab (Cosentyx) in Plaque Psoriasis - Trying To Be Different in a Crowded Space

Current treatments of psoriasis and psoriatic arthritis

Long term safety data is the key for gaining acceptance by Dermatologist

Panobinostat (UR, multiple myeloma, oral HDAC inhibitor) - negative recommendation from FDA and safety concerns coupled with no improvement in overall survival

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Key milestones

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Competitive pressures on Victoza: Semaglutide needs to show at least comparable efficacy to Trulicity

Dulaglutide Phase III data non-inferior to Victoza suggests slightly better efficacy with once weekly advantage

Dulaglutide Efficacy and safety data comparison based on ADA conference vs. Victoza (AWARD-6)

Insulin Franchise: Bio-similar insulin's and Novel Insulin's impact cannot be neglected
Liraglutide 3mg obesity (Saxenda): FDA advisory committee voted in favor (14-1) and approved

Clinical safety and Efficacy from SCALE study vs. Contrave

Pricing and Safety likely to hamper the market reimbursement and uptake, but delayed progression to pre-diabetes may help

Regulatory concerns of pancreatitis, thyroid cancer & CV risk for high dose regimen in obesity

Haemostasis franchise - Turoctocog (NovoEight), NovoThirteen (Cartridecacog), N8-GP
Haemophilia A market size and competition – Novoeight competing long-acting pipeline product from Biogen Idec / Sobi, but may score with a first mover advantage in Hemophilia A

Key milestones

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COMPANIES COVERED:

AstraZeneca

GlaxoSmithKline

Merck

Merck KGaA
Novartis
Novo Nordisk

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